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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/685,081	10/14/2003	Martin R. Hodge	MPI00-268DVIM	5030

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EXAMINER	
HUTSON, RICHARD G	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 03/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/685,081	HODGE, MARTIN R.	
	Examiner	Art Unit	
	Richard G. Hutson	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-12 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-12 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 10/14/2003 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 10/2003.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-12 are at issue and are present for examination.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper."

Applicants filing of information disclosure statement, file on 10/14/2003, is acknowledged.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-12 are directed to all possible methods for identifying a compound which binds to a polypeptide, comprising contacting any polypeptide with or without a target molecule with a test compound and determining whether the polypeptide binds to the test compound, wherein the polypeptide is encoded by a nucleic acid comprising the nucleotide sequence of SEQ ID NO: 1.

The specification, however, only provides the representative species of those methods of use of the polypeptide having the amino acid sequence of SEQ ID NO: 2, encompassed by these claims. There is no disclosure of any particular structure to function/activity relationship in the single disclosed species. The specification also fails to describe additional representative species of these nucleic acid molecules encompassed by the claimed genus, by any identifying structural characteristics or properties other than the kinase activity, which is not a limitation of the rejected claims.

The specification discloses only a single species of the claimed genus (i. e. those methods of use of the protein comprising the amino acid sequence of SEQ ID NO: 2, wherein said protein has kinase activity) which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed. Given this lack of additional representative species as encompassed by the claims, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize applicants were in possession of the claimed invention.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for those methods for identifying compounds which bind to a 14189 polypeptide which involve the use of the polypeptide having the complete amino acid sequence of SEQ ID NO: 2 and having kinase activity, does not reasonably provide enablement for all methods for identifying a compound which bind to any polypeptide, comprising contacting the polypeptide with or without a target molecule with a test compound and determining whether the polypeptide binds to the test compound, wherein the polypeptide is merely encoded by any nucleic acid comprising a nucleotide sequence of SEQ ID NO: 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in In re Wands (858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)) as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claim(s).

Claims 1-12 are so broad as to encompass any possible method for identifying a compound which binds to a polypeptide, comprising contacting a polypeptide with or without a target molecule, with a test compound and determining whether the polypeptide binds to the test compound, wherein the polypeptide is encoded by any nucleic acid comprising a nucleotide sequence of SEQ ID NO: 1, wherein said polypeptide has an undisclosed function/activity.

The scope of the claim is not commensurate with the enablement provided by the disclosure with regard to the utility of the methods broadly encompassed by the claims. The claims rejected under this section of U.S.C. 112, first paragraph, do not place any functional limits on the recited polypeptides and only minor structural limitations on the recited polypeptides. It would require undue experimentation of the skilled artisan to practice the claimed methods of use of any polypeptide having an undisclosed function/activity.

The specification is limited to teaching the use of those methods for identifying compounds which bind to a 14189 polypeptide which involve the use of the polypeptide having the complete amino acid sequence of SEQ ID NO: 2 and having kinase activity In view of the great breadth of the claims, amount of experimentation required to practice and use the claimed methods, the lack of guidance, working examples, and unpredictability of the art in predicting function from a polypeptide primary structure (e.g., see Ngo et al. in The Protein Folding Problem and Tertiary Structure Prediction, 1994, Merz et al. (ed.), Birkhauser, Boston, MA, pp. 433 and 492-495, Ref: U, Form-892), the claimed invention would require undue experimentation. As such, the

specification fails to teach one of ordinary skill how to perform and use the full scope of the nucleic acid molecules encompassed by this claim.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including all methods for identifying a compound which binds to any polypeptide, comprising contacting the polypeptide with or without a target molecule, with a test compound and determining whether the polypeptide binds to the test compound, wherein the polypeptide is merely encoded by any nucleic acid comprising a nucleotide sequence of SEQ ID NO: 1. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of those methods having the necessary steps and the desired results is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

The invention of claims 1-12 appears to require the cDNA insert of the plasmid deposited with the ATCC as Accession Number PTA-2333. Since the cDNA insert is essential to the claimed nucleic acid molecules, it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. This cDNA insert is not fully disclosed, nor has it been shown to be publicly known and freely available. The enablement requirements of 35 U.S.C. § 112 may be satisfied by a deposit of the cDNA insert.

It is noted that applicants have deposited a plasmid containing the human kinase cDNA insert under the Budapest treaty at the American Type Culture Collection ATCC), but there is no indication in the specification as to public availability. As the deposit was made under the terms of the Budapest Treaty, an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain comprising the plasmid containing the cDNA insert has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of the patent, would satisfy the deposit requirement made herein.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-6, 7, 8 and 9-12 are rejected under 35 U.S.C. 102(e) as being anticipated by Yan et al. (U.S. Patent No. 6,413,756 B2, filed 12/19/2000, but granted priority to 6/6/2000).

Yan et al. teach a 1868 bp nucleic acid molecule which has a best local similarity score of 96.5 % identity to instantly disclosed SEQ ID NO: 1 and Yan et al. identify this nucleic acid as encoding a human kinase. Yan et al. further teach a vector comprising said nucleic acid and a host cells transformed with said vector. Yan et al. further teach fusion proteins in which the above encoded kinase is attached to heterologous sequences such as poly-His fusions etc... Yan et al. further teach methods for identifying compounds which bind to the disclosed polypeptides, comprising contacting the polypeptide as part of a cell free system or immobilized and a cell comprising said polypeptide, with a test compound and determining whether the polypeptide binds to the test compound, wherein the polypeptide is encoded by a nucleic acid comprising the nucleotide sequence of SEQ ID NO: 1. Yan et al. further teach methods for identifying compounds which bind to the disclosed polypeptides, comprising contacting the polypeptide as part of an assay mixture comprised of the kinase polypeptide and its target molecule immobilized, with a test compound and determining whether the polypeptide binds to the test compound, wherein the polypeptide is encoded by a nucleic acid comprising the nucleotide sequence of SEQ ID NO: 1.

Thus Yan et al. anticipates claims 1-6, 7, 8 and 9-12.

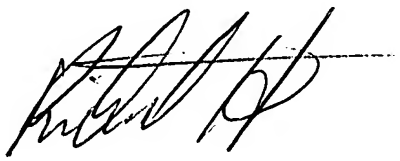
Remarks

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G. Hutson whose telephone number is 571-272-0930. The examiner can normally be reached on M-F, 7:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Richard G Hutson, Ph.D.
Primary Examiner
Art Unit 1652

rgh
3/6/2006